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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,373	11/25/2003	Douglas I. Hepler	02-1198-A	6016

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,373	HEPLER ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1-20-04, 8-9-04, 5-22-06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims included in the prosecution are 1-42.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell (6,045,827) in view of Fisher (5,738,869) of record, Mezei (4,937,078) also of record by themselves or in combination.

Russell discloses a method of treating equine laminitis using a liposomal composition containing a non-steroidal anti-inflammatory drug (NSAID). The drugs include alcoflenac, amfenac, felbinac and others (abstract, col. 1, lines 5-67; col. 4, lines 5-20; col. 6, line 50 through col. 7, line 7; examples and claims). What are lacking in Russell are the teachings of the use of diclofenac in the liposomes; also lacking are the teachings of the inclusion of vitamin E, ethanol and propylene glycol.

Fisher teaches topical compositions containing liposomes encapsulating diclofenac. The formulations further include vitamin E acetate and alcohols. The alcohol mixture taught by Fisher is isopropanol and propylene glycol, which enhances the penetration of diclofenac. Fisher discloses that diclofenac is an example of a NSAID,

which is employed extremely often, specifically in view of its problem free and well-established clinical efficacy (abstract, col. 1, lines 29-40; Table 1 and claims). According to Fisher the efficacy of diclofenac depends greatly on the capacity of the preparation to allow the drug to penetrate the intact skin and the addition of vitamin E acetate to the solution of diclofenac as the drug, PL and alcohols leads to an unexpectedly high skin permeation (example 2).

Mezei while disclosing a method of providing analgesia teaches essentially the same claimed liposomal compositions except that the active agent is not NSAID (phospholipid, ethanol, propylene glycol and vitamin E acetate). Mezei's preparations contain an analgesic (abstract, Examples, Example 1 in particular). According to Mezei, using the formulation one can obtain more pronounced analgesic effect with smaller amount of analgesic since lipid vesicles facilitate the transport of the analgesic through stratum corneum barrier (col. 5, lines 25-52).

The use of diclofenac as the NSAID in the method of treating equine laminitis of Fisher would have been obvious to one of ordinary skill in the art since diclofenac is employed extremely often, specifically in view of its problem free and well-established clinical efficacy as taught by Fisher. The use of an alcohol mixture and vitamin E acetate along with diclofenac would have been obvious to one of ordinary skill in the art since according to Fisher these unexpectedly enhance the penetration of topically applied diclofenac. Although Fisher does not teach ethanol instead of isopropanol, one of ordinary skill in the art would be motivated to use any lower alcohol with a reasonable expectation of success. One skilled in the art would be further motivated to use ethanol

since the reference of Mezei shows the use of ethanol in combination with propylene glycol, vitamin E acetate and liposomes for achieving greater analgesic effect with smaller amounts of the drug. The criticality of the amounts of the drug and the protocol of administration in instant claims 3-6 is not readily apparent to the examiner since these are manipulatable practiced by an artisan to obtain the best possible results.

3. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell (6,045,827) in view of Fisher (5,738,869) of record, Mezei (4,937,078) also of record by themselves or in combination as set forth above, further in view of Grace et al (Journal of Rheumatology, 1999 of record.

The teachings of Russell, Fisher, and Mezei have been discussed above.

Grace et al in a double-blind study with patients with osteoarthritis of the knee find a significant improvement in those treated with 2 % diclofenac in a lecithin formulation compared to placebo (abstract).

One of ordinary skill in the art would be motivated to use diclofenac as the NSAIDs taught by Russell since the reference of Grace et al show the effectiveness of diclofenac and lecithin combination in the treatment of osteoarthritis.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,936,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent and instant claims are drawn to a method of treating lameness in horses using the same composition containing diclofenac. Patented claims recite specific amounts of diclofenac (1 %), propylene glycol (5 %), ethanol (6 %), vitamin E acetate (1 %) and phospholipid (10 %) whereas instant claims recite ranges of the components encompassing the percentages in the patented claims. It would have been obvious to one of ordinary skill in the art to vary the amounts of diclofenac and other components in the patented claims to obtain the best possible results. Such manipulations are deemed to be within the skill of the art. Since diclofenac is an anti-inflammatory NSAID it would have been obvious to one of ordinary skill in the art to use the composition in the patented claims to treat osteoarthritis in a horse with a reasonable expectation of success. Treating lameness or laminitis and osteoarthritis are obvious variants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK